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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,528	06/23/2000	Jan Eirik Ellingsen	06275-199001	9997

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BOSTON, MA 02110

EXAMINER

CULBERT, ROBERTS P

ART UNIT	PAPER NUMBER
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1763

DATE MAILED: 06/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/602,528

Applicant(s)

ELLINGSEN ET AL.

Examiner

Roberts Culbert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23,27,34,44,83 and 84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23,27,34,44,83 and 84 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 23, 27, 34, 44, 83 and 84 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO94/13334 to Ellingsen et al. in view of U.S. Patent 4,024,679 to Gaffar.

Ellingsen et al. teach a process of treating a metallic bone implant consisting essentially of treating the metallic bone implant with an aqueous solution containing fluoride ions in a concentration greater than 0% and up to 3% (Page 3, Lines 1-17)

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Ellingsen et al. do not teach that the aqueous solution is free from sodium and sodium ions, and being a solution of a fluoride selected from the group consisting of lithium fluoride, cesium fluoride, potassium fluoride, ammonium fluoride, stannous fluoride, or any combination thereof. (Col. 2, Lines 56-63)

However, Ellingsen et al. do teach that the treatment process in general comprises *"treating the said implant with an aqueous solution containing a soluble fluoride salt, which solution is of pH 2.5 to pH6."* And that *"the improved biocompatibility is thought to be due, at least in part, to fluoride being retained on the surface of the treated implant"*

Gaffar teaches that preferred water-soluble fluoride ion sources include sodium fluoride, potassium fluoride, ammonium fluoride and stannous fluoride. (Col. 9, lines 1-17)

It would have been obvious to one of ordinary skill in the art at the time of invention to use the water-soluble fluoride ion sources of Gaffar in order to provide a suitable water-soluble fluoride ion source in the method of Ellingsen et al. The selection of a known material based on its suitability for its intended use supports a prima facie obviousness determination. See *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960)

Furthermore, Gaffar teaches that sodium fluoride, and other alkali metal and stannous fluorides are equivalents for the purpose of providing a fluoride ion in water, and it has been held that substitution of one art-recognized equivalent for another is prima facie obvious. See *In re Fout*, 297, 213 USPQ 532 (CCPA 1982).

Claims 27 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO94/13334 to Ellingsen et al. in view of U.S. Patent 4,024,679 to Gaffar and in further view of U.S. Patent 4,746,532 to Suzuki

As applied above, Ellingsen et al. teach the method of the invention substantially as claimed, but do not teach that the implant has a surface layer constituted by a metallic oxide such as titanium oxide.

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However, Ellingsen et al. teach that the invention is suitable not only for treatment of titanium or titanium alloy, but also for coated metallic implants such as hydroxyapatite-coated titanium. (Page 3, Lines 7-11)

Suzuki teaches that it is known to coat metallic implants with ceramics such as hydroxyapatite calcium phosphate, titanium oxide, and combinations thereof. (Col. 3, Lines 1-5)

It would have been obvious to one of ordinary skill in the art at the time of invention to apply the fluoride post-treatment of Ellingsen et al. in view of Gaffar to an implant coated with ceramic such as titanium oxide or hydroxyapatite, since Ellingsen teaches that the treatment is well-suited for treatment of a coated metallic implant.

Claim 44, 83 and 84 are rejected under 35 U.S.C. 103(a) as being unpatentable over International Application Publication WO94/13334 to Ellingsen et al. in view of U.S. Patent 4,024,679 to Gaffar and in further view of the admitted prior art.

As applied above, Ellingsen et al. in view of Gaffar teach the method of the invention substantially as claimed, but do not teach post treatment with a solution containing calcium ions. The admitted prior art (Page 7 Lines 10-15) describes post treatment of an implant with a solution of calcium ions comprising precipitating the calcium ions from the solution comprising calcium ions in order to determine the biocompatibility of the treated implant.

It would have been obvious to one of ordinary skill in the art at the time of invention to treat the implant with a solution containing calcium ions, in order to determine biocompatibility of the implant.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the

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mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roberts Culbert whose telephone number is (571) 272-1433. The examiner can normally be reached on Monday-Friday (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Parviz Hassanzadeh can be reached on (571) 272-1435. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

R. Culbert


PARVIZ HASSANZADEH
SUPERVISORY PATENT EXAMINER